UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE:	)	Case No. 19-MD-2875-RBK-JS
	)	
VALSARTAN PRODUCTS LIABILITY LITIGATION	)	
	)	Camden, NJ
	)	April 24, 2019
	)	10:15 a.m.

TRANSCRIPT OF STATUS CONFERENCE
BEFORE THE HONORABLE JOEL SCHNEIDER
UNITED STATES MAGISTRATE JUDGE

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I N D E X

(The following was heard in open court at 12:10 p.m.)

THE COURT: Please be seated. Welcome back to Camden. It doesn't get any better than today, I'll tell you that. It's beautiful. So we're on the record in the Valsartan Products Liability Litigation, MDL Number 2875.

Let me just say, whoever is going to speak today, just if you would just say your name so when the transcript is transcribed, the transcriber knows who's talking. So for the plaintiffs, entry of appearance?

MR. SLATER: Good morning, Your Honor, Adam Slater for plaintiffs.

MR. NIGH: Daniel Nigh for plaintiffs.

MR. HONIK: Good morning, Your Honor, Ruben Honik.

MS. WHITELY: Conlee Whitely for plaintiffs. Good morning.

THE COURT: Good morning. Defendant?

MR. GOLDBERG: Your Honor, Seth Goldberg and Jessica Priselac for the Prinston defendants.

MS. COHEN: Good morning, Your Honor, Lori Cohen on behalf of the Teva defendants.

MR. SMITH: Good morning, Your Honor, Richard Smith on behalf of Torrent Pharma, Inc.

MR. TRISCHLER: Good morning, Clem Trischler for Mylan Pharmaceuticals, Inc.

THE COURT: So this is the first time we're getting

together for a dual session so let me try and explain how we work things and how things go. I envision myself sort of like an icebreaker or a snowplow on a train. Did you ever see those? They go through the snow.

My job is I'm going to clear the way and get all the issues out of the way so that when we get together with Judge Kugler this afternoon, hopefully everything will go smoothly. Judge Kugler obviously is captain of the ship. He makes the final decisions.

The way we work things is typically all discovery issues I'll handle. Depending upon what the issue is, you know, I'll defer to him. The service issue, he's going to address and decide if it comes to that.

The discovery confidentiality order, hopefully we can get that resolved today. I'll deal with that. The core issue is discovery, I'll deal with that.

That's the way we typically work things but we're in very close contact with each other and we communicate regularly about how to handle the case. The goal is we don't want to jam anything down the parties.

But on the other hand, we're not going to let the parties litigate the case at their whim and just do things whenever they feel like it. We want to move the case along. So that's how it goes so however long this conference takes, we'll be here and then what is it, 1:30 we get together in the

afternoon? Okay. I have your agenda. I want to go through all the issues on the agenda but some issues we won't resolve until this afternoon.

But the first thing I want to address is the organization of the parties and liaison counsel -- how we're going to deal with. It looks like the plaintiffs are straightened out. Thank you for your submission.

I guess, Mr. Slater, we'll need and we'll confirm and Judge Kugler will approve the setup this afternoon, but I take it we'll need an order just confirming that.

MR. SLATER: Correct, Your Honor, and we'd be happy to after the afternoon session. There's actually some modifications to what we submitted. There were a couple of errors or changes in the last couple days so we'd be happy to, if it's approved, we can give you and Judge Kugler any of the small changes and then we'd be happy to submit an order.

THE COURT: Fine. I know one thing that you'll explain this afternoon is Judge Kugler just wants to be satisfied that everyone had a fair opportunity, if they wanted to participate, could participate and there was transparency in the process. I looked at the list, there's a lot of new names on the list so that's terrific.

Okay, let's go to the defendants. It's not -- at least it's not clear to me how the defendants are organized yet, and I think I've expressed to you that after the call we

had two weeks ago, I'm just not satisfied with -- and maybe it's early but hopefully we'll clarify this, it's just unacceptable to get answers from the four of you that you stand up and talk well, I'm only talking on behalf of my client. Can't do that.

We can't do that in this case. And we also have a concern whether the lead group is representative of the entire defendants. I assume, I don't know for sure, that all of you represent API manufacturers and possibly others in the chain, but there's people behind you who have a much less dynamic role in the case and obviously they want to -- you know, do as little work as possible.

I'm not sure that the four of you can represent their interests so somehow, some way, we have to get the defendants organization straightened out so that certainly there's going to be differences.

But, you know, we can't talk to 20 different lawyers or four different lawyers and get four different positions. We -- you have to coalesce and come up with a consensus. So what do you suggest we do and how do we deal with that problem?

MR. GOLDBERG: Thank you, Your Honor, Seth Goldberg. We have -- and since Your Honor -- since our last call, we certainly have discussed that with our defense colleagues. At least with respect to the issues that are before the Court today, this group speaks on behalf of all the defendants. That

said, we have -- there are certain issues where we have invited the defendants at different levels of the supply chain to raise particular issues with us that we will raise on behalf of them.

For instance, there are defendants that may not feel that they should be providing discovery. We can speak for them on those issues when we get to core discovery. There are some parties here that are still not represented. That presents a different issue.

What our plan is, at least for right now, is to proceed with the four defendants here as the executive committee, to invite defendants at different levels of the supply chain as necessary or as they desire to participate in things like the ESI protocol, protective orders and things like that to make sure their input is accounted for as those issues get developed.

THE COURT: Am I correct that the four of you -- I know you represent multiple parties -- but the four of you represent or will represent API manufacturers?

MR. GOLDBERG: Correct.

THE COURT: Okay.

MR. GOLDBERG: API manufacturers and finished dose manufacturers.

MR. SMITH: Yes, Your Honor -- I'm Richard Smith with Torrent. I do not represent an API manufacturer, only a finished dose manufacturer, although I'm also in close contact

with others down the chain in the supply chain due to indemnity relationships that we have with others down the chain.

THE COURT: At the present, you don't represent an API manufacturer but is there a Torrent API manufacturer that eventually will get into this case one way or the other?

MR. SMITH: No, Your Honor.

THE COURT: Okay.

MR. SMITH: The top of the pyramid of Torrent is solely a finished dose manufacturer.

THE COURT: In the United States?

MR. SMITH: No, in India. The top of the pyramid is in India, but that would be a finished dose manufacturer exclusively and not an API manufacturer.

THE COURT: Well, who did you get your API from?

MR. SMITH: We received it from others at this table.

THE COURT: Okay. How about the other?

MR. TRISCHLER: Good morning, Your Honor, Clem Trischler once again. My client are the Mylan entities. And representative of this group are, I think it's fair to say, are API manufacturers, finished dose manufacturers, and distributors.

What we do not have in our -- in our group are essentially retailers and then, you know, we certainly recognize that at the retail level of our leadership group as presently constituted does not include defendants who have been

sued at the retail level. We would certainly invite anyone in the defendants' group that wanted to take a leadership role on that issue to participate with us.

Thus far I think we have been in regular contact with one another . As a defense group, I think as a whole, those parties that have been served are happy with the leadership structure as it's currently constituted, but as issues arise, we would certainly hope into inviting others. We understand the Court's concern.

We do as a whole speak for the defendants who are here. The one issue that I think the Court is concerned with -- and I can understand why -- is, you know, there are -- there are defendants who have not been served and who have chosen, which I think is their right, not to participate. So that presents a unique issue I think for any of us.

We certainly can't speak for an entity that hasn't appeared in the lawsuit and has not been in communication with us, but we can represent and speak to the interests of the defense group that's here and actively participate in the litigation. We have been doing that, that's our intent, to continue to do that.

THE COURT: Bear with me. Let me look at my notes for just a moment.

MR. TRISCHLER: Certainly.

(Pause in proceedings)

THE COURT: So you represent Mylan Pharmaceuticals, Inc., right?

MR. TRISCHLER: Yes, Your Honor.

THE COURT: Okay. Mylan N.V., are they an API manufacturer?

MR. TRISCHLER: No, sir. Mylan N.V. is a parent corporation that had no direct role with respect to -- to Valsartan, other than its ownership of wholly owned subsidiaries that were involved in the distribution chain. The API supplier is Mylan Laboratories, Ltd in India.

THE COURT: Okay. So am I just naive to think that you're not in contact with Mylan -- what did you say -- Laboratories --

MR. TRISCHLER: Mylan Laboratories, Ltd.

THE COURT: -- in India, and they don't know exactly what's going on in this case?

MR. TRISCHLER: Oh, they certainly know what's going on in the case, Your Honor. I've certainly been in contact and communication --

THE COURT: And eventually --

MR. TRISCHLER: -- with them.

THE COURT: -- you're going to represent them probably in this case, right?

MR. TRISCHLER: Yes, sir.

THE COURT: After they're served, right?

MR. TRISCHLER: Yes, sir.

THE COURT: Okay. So at present, you don't represent an API manufacturer, but in the future you will?

MR. TRISCHLER: That is correct.

THE COURT: Okay. So you have an API manufacturer, Mr. Goldberg has an API manufacturer. Ms. Cohen?

MS. COHEN: Good morning, Your Honor. To the Teva defendants, both the -- the US entity and finished dose manufacturer.

THE COURT: Teva Pharmaceuticals, Inc?

MS. COHEN: Yes. And then Teva Pharmaceuticals Industry (sic), Ltd is the Israeli company I think I mentioned last time was when we discussed it with plaintiffs --

THE COURT: Teva --

MS. COHEN: Pharmaceutical -- Teva Pharmaceutical, singular -- Industries, plural, Limited -- ,Limited. That's the foreign entity -- Israeli entity that will also be a finished dose manufacturer, and they have been served. And we are not objecting to that service in the MSP recovery case, so I know that's for a later discussion.

But again, so we will not have an API entity and I would just echo what my colleague said, you know, that number one, we're certainly open to other categories joining. We are certainly not being restrictive and I think that Mr. Trischler said it very well, that we currently cover API manufacturers,

finished dose manufacturers, the distributors, and we're missing sort of the -- the repackager retailer level.

That's the only level that's not covered right now, but we certainly, you know, have been in a lot of communication and we would be open to having someone join if they wanted to.

But we've again had a lot of communication. And your -- your point, Your Honor, was well taken that we can't say that -- or shouldn't say that we are just representing our own client. We're here as the liaison executive group, and we understand that.

THE COURT: Ms. Cohen, who is Teva's API manufacturer?

MS. COHEN: Again, as was said by Mr. Smith, people at this table.

THE COURT: Who supplied the API to your client?

MS. COHEN: Right, mainly --

THE COURT: All people at this table?

MS. COHEN: Yes --

THE COURT: Okay.

MS. COHEN: -- entities who are here --

THE COURT: Okay.

MS. COHEN: -- exactly, Your Honor.

THE COURT: All right.

MS. COHEN: It's a little more complex than I, you know --

THE COURT: All right.

MS. COHEN: -- can get into exactly but --

THE COURT: So I'm sure you've given this some thought, each of you represents, you know, companies in the corporate chain, but can't you foresee down the road that there might be a conflict between an API manufacturer and a finished dose manufacturer?

Suppose -- not in the same corporate chain, but there's a lot of people out there behind you and let's say there's a lawyer out there who represents just a finished dose manufacturer, doesn't that company have a theoretical conflict with the -- with its API supplier?

MS. COHEN: I mean I guess theoretically right now, you know, I think every -- everybody has been in unison and again, I think the only group that's not currently part of this group's constitution would be the lower level on the chain, that is the retail level, so --

THE COURT: Yes, I know --

MS. COHEN: -- you know --

THE COURT: -- Ms. Cohen, but I think the difference is this. Everyone at the table is in a corporate chain, so each of you has -- you know, doesn't have a conflict because you're in the same corporate chain. Clearly, they're not going to assert claims against each other.

But there are people out there -- say there's a

finished dose defendant behind you who is not in your four corporate chain. Wouldn't they have a claim against their API manufacturer?

MS. COHEN: You know, I think it would be hard to speak to that --

THE COURT: Or supplier?

MS. COHEN: -- right now, but we certainly I think -- I think we could be -- we are certainly open to having more people and I will say this, Judge. I think it was yesterday that we received -- or maybe it was two days ago, you know, in the afternoon that we received the plaintiff's new structure with a lot of different names.

So we saw that and thought well, that sort of changes the dynamic a little bit because they have different categories, and so we thought we would at least, you know, discuss it with our group, the defense group, having seen that, I think about if we wanted to add more people based on that, because that -- that was the first time we saw it was two days ago.

THE COURT: Why don't we do this, Ms. Cohen.

MS. COHEN: Hm-hmm.

THE COURT: I am opening up to everybody, there's going to be a break between this conference and the conference this afternoon, why don't you just chew on our concern that your interests out there behind the bar are being protected.

I just wonder if there should be someone at that table who represents the finished dose manufacturers who aren't in the same corporate chain as the API supplier, and I wonder if there should be someone at that table who just represents maybe a retailer who is -- who wants to do no work on the case, --

MS. COHEN: Yeah.

THE COURT: -- right?

MR. SMITH: So, Your Honor, Richard Smith for Torrent --

THE COURT: To make the -- to make the defense group more representative, to make the defense executive committee more representative.

MR. SMITH: Your Honor, Richard Smith for Torrent, I believe I do represent that theoretical defendant who is solely a finished dose manufacturer who may very well have theoretical conflicts with others who are serving on the executive committee of the defendants.

We do not have an API manufacturer. We supply our API from others who are defendants in this case. We may very well have theoretical claims against those API manufacturers, just as Your Honor suggests, and I'm here at this table representing those interests.

I'm also in constant contact with others, as I mentioned, at the retailer level who Torrent has committed to

indemnifying such as, just to give an example, Wal-Mart, who we are indemnifying. And we are in constant contact with Wal-Mart to make sure that their interests are aligned with ours because we really in an indemnity relationship do not want to be in a situation where Wal-Mart is being prejudiced because we are then in that indemnity relationship with them.

So those -- those interests we believe are fairly covered here and in our calls on the defense side, we are very careful to make sure that everyone has a voice and everyone is being able -- has the opportunity to their positions.

THE COURT: Why don't you chew on what I'm raising over the break to see if the defense executive committee could be more representative of the entire group.

Maybe there's a person or persons out there who represents a small defendant or a defendant who thinks they have small exposure who will sit at the table and can communicate their particular interests.

MR. SMITH: We will do that, Your Honor. I think it's a bit of a chicken and egg problem for us on the defense side insofar as in the first conference with the Court, the Court expressed a lot of concern about the number of defendants who are in this case and in particular, those very small defendants who the Court expressed concern might not be appropriately in this case.

THE COURT: That's exactly right --

MR. SMITH: And --

THE COURT: -- and that's why I personally think someone who represents those interests should be at that table to advocate why they shouldn't be in this case.

MR. SMITH: And those defendants are very reluctant to sit at this table because they do want out of this case and strongly believe they shouldn't be here. Thank you, Your Honor.

THE COURT: You understand the Court's concern.

MR. SMITH: Yes, we do.

THE COURT: Okay.

MR. SMITH: We -- we will noodle on that.

THE COURT: The plaintiff has identified liaison counsel for the Court and with the defendant and liaison counsel to I guess communicate with the plaintiff's group. Is there a similar liaison counsel appointed for the defense? Who will the Court go to in the first instance as liaison to the Court?

MR. GOLDBERG: Your Honor, I think at this point it would be Duane Morris, myself and Ms. Priselac.

THE COURT: Okay, great. So eventually that will be -- when we get this order together, let's see, we'll get the defense-plaintiff organization together and might as well do the defense in the same order, okay?

So let's go -- let's just go through the agenda and

like I said, some issues we'll defer to this afternoon. We've discussed the leadership issue and we're done with that. The second issue is service on the foreign defendants.

In my view, the biggest concern here is this. Are the foreign defendants, the key API suppliers who haven't been served yet, are they taking the position that until they're served they don't have to provide any discovery in the case? That's my biggest concern.

MR. SMITH: Your Honor, Richard Smith on behalf of Torrent. I have spoken with --

THE COURT: But you don't represent an API supplier.

MR. SMITH: That is correct, Your Honor, which is why I think we are perfectly representative of the defendant group.

THE COURT: But how could you talk for them?

MR. SMITH: I -- I am talking on their behalf because Your Honor has instructed the defense --

THE COURT: I don't understand --

MR. SMITH: -- executive committee to be able to do so.

THE COURT: -- you don't represent them.

MR. SMITH: I think there's a difference though, Your Honor, between the foreign entities who nobody in this courtroom represents --

THE COURT: Okay.

MR. SMITH: -- who have not been served and who will

very possibly not ever be represented by any lawyer in this courtroom and the folks like Torrent who -- Torrent Pharma, Ltd who ultimately will be represented by me when they are served or we may reach an agreement to waive certain --

THE COURT: Are there any API suppliers in the United States, or are they all foreign companies?

MR. SMITH: I do not believe there are any API manufacturers in the United States. I think all of them are foreign entities. And one in particular that Your Honor is asking about now is Hetero Labs, Ltd, which is an Indian API manufacturer who has been sued in this case but has not been served and is not represented by counsel in the case.

THE COURT: But Hetero USA is represented.

MR. SMITH: That is correct, Your Honor. So we have spoken with Hetero USA's counsel. Hetero --

THE COURT: Is Hetero USA out there?

MS. POLETTO: I am, Your Honor.

THE COURT: Lucky you. Okay.

MS. POLETTO: We have spoken --

THE COURT: Do you want to just put your name on the --

MS. POLETTO: Sorry?

THE COURT: Are you Ms. Poletto?

MS. POLETTO: I am.

THE COURT: Welcome. Okay, so what's -- what's their

position? Do you want to -- do you want to speak on -- on behalf or do you want to speak on their behalf?

MR. SMITH: Well, maybe I can speak a little globally and then if you'd like specific --

THE COURT: Okay.

MR. SMITH: -- questions, we can do that. There are certain manufacturers, Your Honor, certain foreign defendants whose relationship with their US subsidiary is not the same as the relationship that Torrent has with its -- its foreign parent.

Insofar as those entities really do operate as at arm's length, they -- the lines of communication between the foreign entity and the US entity is not as clear, and it is not at all certain in those instances that the counsel that the US entity has chosen to represent in this case will be chosen by the parent corporation.

Those counsel, I can inform the Court, are having difficulty reaching out even through their client to the -- the foreign parent corporation. It is truly an arm's length relationship between those entities.

For purposes of core discovery, we have heard the Court's concern about moving this case forward. We understand that the US subsidiaries have been served in those cases or with respect to those relationships, and we have asked the US subsidiaries do they have access to -- I think it's the same

question Your Honor asked two weeks ago in an email -- do they have access to the core discovery materials and will they produce those core discovery materials even though they make take the position that those materials belong to the foreign parent.

And in almost every instance, those entities have said yes, to the extent that we have those materials, we will produce them because we believe that we have sufficient custody, possession and control over those materials here in the United States.

THE COURT: You just said “to the extent we have them.” Well if they have them, there’s no issue about custody --

MR. SMITH: Yes --

THE COURT: -- or control or possession.

MR. SMITH: So --

THE COURT: The question is -- take an example, an FDA inspection of the facility and a 483 report, okay, hypothetical. US company doesn’t have it, but obviously the foreign company has it. Is that going to be produced?

MR. SMITH: To the extent that the US entity has -- Your Honor is asking -- talking about the ancillary discovery to inquire whether the US entity has sufficient --

THE COURT: If they have it, it’s easy.

MR. SMITH: Yeah, if they have it it’s easy --

THE COURT: If they don't have it, what happens? Are they going to get it from the foreign company?

MR. SMITH: They are seeking approval to do so, and what I can tell Your Honor is on the list that the defendants have circulated in terms of core discovery, those easily identifiable documents that we have said we will able to produce in core discovery, we have been able to secure a decision from all of the defendants as to whether they have those documents and are willing and able to produce those documents and we can go through each one of them and I can tell you on behalf of these defendants whether they can or not.

With respect to the 11 categories of documents that we believe are far-ranging and not subject to core discovery, those defendants have not -- that issue hasn't really been put before those defendants to be able to say yes, this broad category of documents I'm capable of producing or I'm incapable of producing.

So we've done our homework on the defendant's side core discovery, but we don't -- we can't predict what else might be ordered as far as discovery, but we are ready, willing and able to go back to those defendants and say with respect to any easily identifiable document that the Court may say is part of core discovery, are you able to produce that document or not and provide an answer to the Court. But again, we have done our homework with respect to our position on core discovery.

THE COURT: Bear with me one moment.

(Pause in proceedings)

THE COURT: Who are -- let's clarify for the record so the record is clear, who are the API manufacturer -- foreign manufacturer-suppliers? Why are they? One is ZHJ we know obviously.

MR. GOLDBERG: Your Honor, I have -- I have a few lists of defendants that you requested may be helpful, they don't identify the defendants in that way, although I think they did, but if it's helpful for you to have the lists so you can mark them --

THE COURT: Is it attached to the --

MR. GOLDBERG: No, I brought them here --

THE COURT: Okay, sure.

MR. GOLDBERG: -- and I can hand them up.

(Pause in proceedings)

THE COURT: Thank you. Oh, great. Thank you. So the API manufacturers -- the foreign API -- Z-H -- this has it as ZHP, I call them ZHG. Teva Pharmaceuticals, Inc, are they an API manufacturer-supplier?

FEMALE COUNSEL: No. No, Your Honor, they're a finished manufacturer.

THE COURT: Finished?

FEMALE COUNSEL: Yes.

THE COURT: Torrent Pharmaceuticals, Ltd?

MR. SMITH: No, Your Honor, solely a finished dose manufacturer.

THE COURT: Mylan N.V.?

MR. TRISCHLER: No, Your Honor, just -- Mylan N.V. is just a holding company.

THE COURT: Mylan Laboratories?

MR. TRISCHLER: Yes, sir.

THE COURT: They're an API manufacturer --

MR. TRISCHLER: Yes --

THE COURT: -- supplier?

MR. TRISCHLER: Yes, sir.

THE COURT: Hetero Labs, Ltd?

MR. SMITH: Hetero Labs is an API manufacturer, Your Honor.

THE COURT: Hetero Drugs, Ltd?

MR. SMITH: Your Honor, my information is that Hetero Drugs, Ltd is not involved in manufacturing either Valsartan API or its finished dose.

THE COURT: Aurobindo Pharma, Ltd? Are they API?

MR. GOLDBERG: Yeah, Aurobindo Pharma Ltd is an API.

THE COURT: Okay. And Arrow Pharm (Malta) Ltd?

FEMALE COUNSEL: Not -- not API, Your Honor.

THE COURT: Okay. So going through that list, there's four API foreign manufacturer/suppliers in the case? Okay.

UNIDENTIFIED SPEAKER: That have been sued -- yes, sir.

UNIDENTIFIED SPEAKER: Did you mention --

THE COURT: That has been sued.

UNIDENTIFIED SPEAKER: Did you mention Zhejiang Huahai? That's the --

THE COURT: ZHP.

UNIDENTIFIED SPEAKER: Correct.

THE COURT: -- is Zhejiang Huahai Pharmaceutical Co., Ltd?

UNIDENTIFIED SPEAKER: Yes.

THE COURT: Okay. So we know Zhejiang is represented, they're in the case. Mylan Laboratories Ltd, they're not in the case?

MR. SMITH: They -- they've not been served --

THE COURT: I'm sorry --

MR. SMITH: -- Your Honor --

THE COURT: Right, not served.

MR. SMITH: -- but we will -- but my client without waiving objections to -- to the service of process, has -- will participate in core discoveries --

THE COURT: Great.

MR. SMITH: -- ordered by the Court.

THE COURT: Okay, great. And then the other two are Hetero -- no one knows who --

MR. SMITH: So Hetero --

THE COURT: Hetero Labs Ltd.

MR. SMITH: Hetero Labs is not represented by counsel in the case. Multiple lawyers in this room have talked with Hetero Labs to notify them of this case and they -- they have not been served, they have not entered any appearance and it's likely that no lawyer in this room will represent them either.

THE COURT: But we have Ms. Poletto for Hetero USA Inc.

MS. POLETTO: I am here, Your Honor, yes.

THE COURT: And they are what?

MS. POLETTO: We are simply the FDA liaison for Hetero Labs, Ltd for the US (inaudible).

THE COURT: What does that mean?

MS. POLETTO: Valsartan.

THE COURT: What does that mean?

MS. POLETTO: The -- when the ANDA is filed, it's done through -- you have to have a US agent in that communications are done through the US agent.

THE COURT: So you're not a --

MS. POLETTO: So basically the (inaudible) communications were not the FDA, their communications that you can't get through labs and want to contact (inaudible). That's our role with regard to (inaudible).

THE COURT: You don't sell? You don't sell anything?

MS. POLETTO: Not Valsartan, no.

THE COURT: So can -- can Hetero USA, Inc. produce whatever core documents are ordered to be produced in the case?

MS. POLETTO: I suppose it depends on what those core documents are that are ordered. The core documents that the defendants have committed to at this point in time, I believe we have most of those in our possession, but I could not represent is that as to the totality of what would be in any of those categories. But I have spoken with Hetero USA and they are willing to produce what they have in their possession.

THE COURT: That's so easy -- they can produce what they have in their possession -- that's easy.

MS. POLETTO: Understood, Your Honor.

THE COURT: Here's a hypothetical. An inspection report that the FDA did of the Indian facility, suppose it's not in Hetero USA's file cabinet.

MS. POLETTO: And likely not.

THE COURT: Can they produce that document?

MS. POLETTO: I can't represent that to you right now, Your Honor, I cannot.

(Pause in proceedings)

MS. POLETTO: I can make further inquiry, but I don't have any direct communication so --

THE COURT: So --

MS. POLETTO: -- it's very -- it's a unique posture

with approving (inaudible).

MR. HONIK: Your Honor, may I interject something at the -- this is Ruben Honik -- at the potential risk of mucking up with the hope that it may offer some clarification in the way we can think about this a little bit, it's not a small matter who the FDA issued the ANDA to, and I say that because none of our clients on the plaintiffs' side -- economic loss, bodily injury loss, nobody bought an API.

Everybody bought from a retailer a finished product that the FDA green-lighted by issuing an ANDA. And why I think that may be relevant a bit to some of the discussion we've had can be illustrated by the following point:

As I look at the status of service on foreign defendants that Mr. Goldberg handed out, there are two Mylan entities. One is Mylan N.V. which is presumably a holding company and actually the parent, it's a Dutch company, and then we've got the API manufacturer which is Mylan Laboratories, Ltd.

And it is so far as I know absolutely true that the API manufacturer in India -- Mylan Laboratories, Ltd was not served. That's -- I believe that to be the case. However, the actual ANDA was issued to an entity called Mylan Pharmaceuticals.

They're located in the US, they're in Canonsburg, Pennsylvania and they have been served. They're not even on

this list and they own the ANDA and they're the ones from whom our clients -- all of our clients bought the product.

And so to the point concerning discovery, it strikes us as likely that with service on the ANDA holder, with service on the parent whose -- whose headquarters is also in Pennsylvania, that that would be an example of a foreign API who notwithstanding the fact that direct service was not made in India, should certainly be able to give us the core discovery if not more in a case such as this.

And there are other examples, we can go through it later when we talk about service, but it relates to discovery and the ability to -- to get the case moving to point out that the entity that has the ANDA -- who's been issued the ANDA without more, could be the only folks sued in this entire litigation.

THE COURT: I think you're getting to the crux of why I'm so concerned about this, and I want to cut through the gunk and just focus on the most important thing.

MR. HONIK: Right.

THE COURT: My concern is -- let's take Hetero for example, plaintiffs are undoubtedly going to ask for FDA inspection reports of the Indian facility, am I right? Am I reading your mind right?

MR. HONIK: Yes --

THE COURT: Okay.

MR. HONIK: -- Your Honor.

THE COURT: Hetero USA is going to take the position probably that they don't have possession, custody or control of those documents -- this is hypothetical, I'm assuming that. What happens?

Then you -- then we get into a whole discovery morass where you want discovery from Hetero USA to show that they have control over Hetero's documents in India, right? Motion practice, depositions, discovery disputes, et cetera, et cetera. I would like to avoid that. You know, this isn't the first case where this has happened.

MR. HONIK: Right.

THE COURT: If I was in Hetero's shoes, but I'm not, I would want to avoid that and I would say okay, I'm going to get the documents and produce them because I don't want to get into a discovery fight about how much control Hetero USA has over Hetero India's documents. That's going to happen, okay?

MR. HONIK: Right.

THE COURT: That's what I'm trying to avoid if possible. If not, you know, they have a right to -- to take whatever position they want. But I understand. You're going to take the position that they have possession, custody or control over the Indian documents. Hetero USA is going to take the position they don't. So what happens? You're going to take discovery, you're going to take a 30(b)(6), you're going

to ask for ESI and we're going to be here on motion after motion after motion. I would like to avoid that if possible.

MR. HONIK: Understood.

THE COURT: So if I can't, I can't and we'll have to deal with it. And then the last API manufacturer/supplier is Aurobindo, is that correct?

MR. SMITH: I do not have information that they are an API manufacturer, but that may be the case. I don't know if Aurobindo's lawyer's (inaudible).

THE COURT: Is Aurobindo in the case?

MS. HEINZ: Yes, Your Honor. Yes, Aurobindo Pharma is an API manufacturer, (inaudible).

THE COURT: Okay.

MS. HEINZ: I only represent Aurobindo Pharma USA however.

THE COURT: Right. Ms. Heinz?

MS. HEINZ: Yes.

THE COURT: Okay. Well, how about let's put you on the spot.

MS. HEINZ: Actually, similar to Mylan, Aurobindo Pharma is the US agent for its parent company which is Aurobindo Pharma Ltd, and in terms of the core discovery that the defendants already agreed to produce, I can tell you that Aurobindo Pharma USA does have access to that information and would be able to produce it.

THE COURT: Okay. But suppose my hypothetical -- FDA inspection reports of your facility in India. If those aren't in your file cabinets, can you get those documents?

MS. HEINZ: I think it's likely, Your Honor.

THE COURT: Okay.

MS. HEINZ: I do have to go back to them and just make sure.

THE COURT: Okay. All right. So I think what we're hearing is just we'll just have to identify the core documents and order them to be produced and we'll find out which documents of the API manufacturers or suppliers aren't produced, and then if plaintiffs want to pursue it, they can.

Which gets us into the service issue, and I think that will be resolved this afternoon, which sort of dovetails into the next issue, the organization of the master complaints. Boy, I was hoping that you would agree to this, but why is there a dispute about this? Why can't you agree to this? Plaintiffs want personal injury, economic and medical monitoring, right?

UNIDENTIFIED SPEAKER: That's correct.

THE COURT: Defendants want personal injury, economic and third-party payer, is that right? Is the difference they want a separate medical monitoring and you don't?

MS. COHEN: And, Your Honor, again, we just received information from -- this is Lori Cohen for the record -- about

the master complaints and how they were reconfiguring them a couple of days ago, so we did put down our position that we understood until that point that it was sort of going to be kind of three buckets, if you will, I think is how we described it -- personal injury, consumer class action and third-party payer as a separate group, and that's what we -- that's what we had talked about at the prior conference with Your Honor.

So I don't think we really would object to them having the medical monitoring in one place or another necessarily, we just wanted to point that out, that we don't think that there is a need for a separate one.

But you know, again I'm not sure that we're going to take a strong adversarial position on that, we just want to again note that we had always envisioned the three different categories as how they were setting up the master complaints and that's why we -- for example, when we get to the profile forms -- and we may not get to that today because we just received their comments this morning.

But we prepared three profile forms to kind of coincide with what we thought the master complaints would be, so we may have to do some reconfiguring of that, and I don't think subject to what the others say at the table, we pointed out that we didn't think there was a separate -- a need for a separate medical monitoring class action because there's only one punitive medical monitoring class action today.

But again, I think probably the plaintiff's call, how they do those -- unless anybody has any other comments there, Your Honor.

THE COURT: Okay. Am I correct --

MS. COHEN: I don't mean to sound wishy-washy but it's just that we -- we had always had like three groups and then we received that and we were still talking about it when we did our physician statement.

THE COURT: Am I correct though that it's -- the foreign companies' position that each of the -- however they're going to do their master complaints, the three categories, you want the foreign manufacturers served with each of the three pursuant to the Hague?

MS. COHEN: We do, Your Honor, and I know that sounds like -- like form over function if you will and perhaps we're segueing into that discussion, but really at the end of the day under due process and constitutional law and all the things we raised last time I know we'll get into with Judge Kugler, we could have insisted on Hague service for every single one, so this is a compromise position.

I know that the plaintiff is saying that their position -- well, it seems, you know, silly that if we -- for example, let's take the Teva entity, the Teva Ltd Israeli entity. They had been served in the MSP recovery case so there's service in that one.

We do believe as our compromise position using my client as an example since we're standing up, that they should be whatever the categories are, at least one official due process Hague service in each community, as our compromise professional accommodation position as opposed to standing on principle and saying I demand ever single one being served.

So -- so I think once we figure out what their -- I using buckets -- types of master complaints and we would like to have each one, and that's our position, Your Honor.

THE COURT: Okay. That's why I think that issue is going to be resolved this afternoon. I can tell you what I think and I think I've related on the last call, I think a very fair compromise would be so long as the foreign API manufacturers/suppliers agree to respond to the core discovery that we're going to order and over the next nine months, whatever discovery we're going to do, I say a fair trade for that is to make the defendants -- I'm sorry, plaintiff serve their three complaints pursuant to the Hague.

I don't see any incremental difference between serving one pursuant to the Hague and three pursuant to the Hague. That's just me talking. I would ask Hetero and Aurobindo and the other one if over the break they can just see if they can agree to that and agree to make a recommendation to the client because I personally think that would be a fair compromise. But we'll resolve that this afternoon.

MS. COHEN: Thank you, Your Honor.

THE COURT: Okay. I know we skipped over core discovery. I want to save that for last because that's a substantive issue. The profile forms, that's not ripe yet?

MS. COHEN: And, Your Honor, I'm happy to -- since I was just standing, jump up here. So our -- on the profile forms again, it sort of does dovetail with this master complaint concept and what's going -- what plaintiff's going to do there.

What we did is after the last time we met, we had a fruitful productive discussion before the last main conference in the side room upstairs, and then the plaintiffs at some point thereafter sent us a draft profile form just for personal injury, we came back and admittedly it was over the weekend I sent them three profile forms to coincide and correlate with what we thought the master complaints would be before we received their latest.

And they this morning while I was driving over here -- I wasn't actually -- I was being driven here -- I received their comments. We haven't even had a chance to look at them yet so I don't think they're ripe yet.

I think a little more discussion and back and forth would probably be helpful, but our vision is that there should be a profile form for each of the categories and again, some of it relates to the core discovery issue because it's a little

bit what's good for the goose is good for the gander, you know.

And if we're going to be truly and limited core easily ascertainable discreet package of discovery on the defense side, then it sort of impacts how much we should expect from their side, so they do go a little bit hand in hand.

So I think once we proceed to hear your thoughts on core discovery and hear what -- you know, now that we know what their master complaints are going to look like, then I think we'll have some additional productive discovery on the current draft so we can reconfigure if one of them right now doesn't match exactly what they're going to do in terms of master complaints, we can easily rework that.

THE COURT: Anything from plaintiffs?

UNIDENTIFIED SPEAKER: Yes. We -- we went ahead and we gave them copies of what our proposed bodily injury plaintiff profile form was. We did that a couple weeks ago and we received their edits on Saturday and we gave them redlines for the bodily injury this morning.

I don't think we're too far apart on those. That's probably something that we can resolve over the next couple of weeks and enter in at the -- the telephone conference, or even earlier than that. Consumer class, we may have those edits to them today. There's just a couple of issues that I wanted to sign off with with the class folks as well on that one.

The TPP is a different story. I believe that that

data is kept in a different function. That profile form I don't think will mirror the bodily injury and the consumer class profile forms so we have to have a little bit more discussion, but we hope to get them our edits on that next week.

THE COURT: Okay. Practically speaking, should we target the end of May to finalize the profile forms. We can discuss it at our conference call in two weeks but let's target the end of May, we'll get them finalized and get the order entered, okay?

MS. COHEN: Yeah, that sounds great. Thank you, Your Honor.

THE COURT: Okay. ESI protocol, I know that's an ongoing process and that may be the most important substantive issue we deal with on the discovery process. Any suggestions how we can move that process along? One of my feelings is I think getting the core discovery to you would help that process.

MR. SLATER: Your Honor, to some extent, we sent them a proposed protocol two or three weeks -- April 8th, so they have --

THE COURT: But is this apart from custodians and search terms, everything else?

MR. SLATER: That would be the next layer, but we're not -- that would be -- that would be overlay.

THE COURT: Okay.

MR. SLATER: We haven't gotten the search terms yet.

THE COURT: Yes.

MR. SLATER: This is just the protocol in terms of form of service, form of production --

THE COURT: Well, that shouldn't be too hard.

MR. SLATER: Well it shouldn't be, but we want to make sure we're on the same page because we're going to -- we're working with our vendor in setting up our system and how things are produced, how the metadata is divided, et cetera, matters.

We told them we took the Benicar ESI protocol which it was the final version, obviously not -- it was -- it was a heavily negotiated document through a major meet and confer process. We litigated that with Your Honor.

You made some calls and we ended -- a couple little things that just and based on development of technology and certain best practices over the last few years --

THE COURT: We're not going to get into the native issue.

MR. SLATER: I'm not getting into that. I think those issues have been resolved. So, you know, our feeling, we gave it to them, they told us on the phone on our meet and confer Monday that they formed a subcommittee and they're looking at it. So in nine or 12 months, we should have a

response --

THE COURT: No, no, no, no, no --

MR. SLATER: -- from the subcommittee.

THE COURT: That's not going to --

MR. SLATER: I'm joking. I'm joking.

THE COURT: No.

MR. SLATER: What I would think is they said they were going to have a response to us next week. We're a little concerned it's taking a while, but we understand they have organizational issues. It's not worth it to go crazy today over it.

Our sense is they're going to come back to us, and we're hoping that there's going to be very little comment because we really think it's a very balanced order because again, it was litigated with very good lawyers and it was litigated before Your Honor.

To the extent there are issues, what we suggest is the same process you put us through in the last litigation which was don't go to -- we asked for 30(b)(6)'s and the whole normal blown up process and you said no, get in a room, spend as much time as you need to, ask your questions, if you can't get answers, come back to me, I'll tell you.

And -- and that's what we would suggest, is an informal meet and confer process that is formal in the sense that the answers need to be provided and if there's a dispute,

we can call you up and let you know. Is that -- if that's okay with the Court, that's what we would like to push on quickly.

THE COURT: Maybe I should clarify. I think the search term "custodians" is going to take some time, but the rest of it, I mean, this has all been done before. Defendants, it would be great if we could put this behind us. Do you think targeting the end of May is unrealistic?

MR. SMITH: Your Honor, Richard Smith. I have the -- I don't know, maybe unwelcome task of being the head of this project for the defendants, I'm looking at the defendants' list and I have 41 different defendants, 41 potentially -- there will be some overlap but many different systems.

I appreciate the fact that it was fully litigated with very good lawyers in the last round, but that was with different vendors and different systems, and I think the fact that it was litigated so hard in the Benicar litigation emphasizes the fact that this is a very important issue.

So I'm trying to herd the cats on the defense side in terms of making sure that I understand what the issues are on the protocol itself, setting aside custodians and search terms and all the rest which I agree can -- can trail, but I have committed to getting back to them next week on the ESI protocol order.

I can tell you already that there are some issues that I'm seeing with the order where it looks like we are

duplicating work and unnecessarily adding work both for the defendants or the producing party and the receiving party.

And so I'm trying to make sure that I have a full compilation of those issues to maximize efficiency for both sides so that we're not duplicating work and putting things out of order. But I am -- I have committed to getting back to them next week.

As far as targeting having this completed by the end of May, I am very hopeful. It will, as you know, depend on the negotiations between the parties, and when I do get back with them next week, what is the response and -- and that's really the issue.

THE COURT: Let's do this. If we can't -- maybe 30 days is a little optimistic to finalize it, but 30 days to at least tee up all the disputes and we'll get them resolved in 30 days and on the heels of that, we'll get that part of the ESI protocol done and just wait for the search terms and custodians.

So all ESI disputes regarding the ESI protocol will be identified in 30 days, and when we have this conference at the end of May, we'll argue it, we'll get it -- if there's any disputes, we'll argue it and decide it.

MR. SMITH: I think that's very fair, Your Honor, although I remain optimistic that we can get back to you in a month and have this more tied up than --

THE COURT: Good.

MR. SMITH: -- than just that.

THE COURT: But you mentioned 41 defendants. Is that every category of defendant? Like for example, have you discussed with plaintiffs whether retailer discovery is going to be appropriate?

MR. SMITH: We have addressed that this week, Your Honor, and the answer from the defendants despite the Court's clear leadings in terms of -- of narrowing the defendants down and getting the ancillary -- what we're calling "minor defendants" out of this case at an early state. The defendants said absolutely not --

THE COURT: Plaintiffs said.

MR. SMITH: Or excuse me -- the plaintiffs said absolutely not, every one of those defendants has to sign off on this ESI protocol on what everybody represented on this ESI protocol, and that is creating substantial burdens on the defense side, Your Honor, and I think unnecessarily so since those defendants should be out of the case.

MR. SLATER: I think there's a lost-in-translation with that, if that's what they're -- the defense understanding was. What we said is there should be one ESI protocol for the litigation. We're not going to have separate ESI protocols.

So it wasn't that we -- the issue of whether or not certain parties are going to provide discovery or what they're

going to provide is a different question that is -- is being discussed and we're going to talk to them about.

But we were just saying we're not going to have a separate ESI protocol for the repackagers and then a separate one for finished dose formulator, and which I don't think it makes any sense to have more than one format of an ESI protocol.

THE COURT: That seems to make sense, right?

MR. SMITH: I think in general it makes sense and in theory it makes sense, but in practical application it means I have 41 different defendants that I have to check with their vendors and make sure that what I say that they're going to produce -- tif images or PDF images, that they're equipped to do that, I mean just to give one example and that's a pretty minor example.

But all of the things in this multiple-page ESI protocol, I have to go to every one of the manufacturers, including the one that only sold 73 bottles of Valsartan to make sure that they're fully equipped to comply with this entire ESI protocol so that they're not left behind in case the Court decides not to dismiss them or the plaintiffs decide not to dismiss them.

At the last hearing, Your Honor, just a month ago we heard from a parade of plaintiff's lawyers who came up and said I'm going to dismiss the Losartan cases. If we dismiss the

Losartan cases, I think this room would be half as large as it is today because there were so many defendants who were in only the Losartan cases.

Well because we're putting the ESI protocol before the -- the horse, then we have to go to each one of these defendants who are in here only for Losartan and only for a couple of bottles and make sure that they can fully comply with every word in the ESI protocol.

Now, I think that's -- that's a tough burden for them when they should be let out of the case. And a month ago, we're told they were going to be let out of the case.

THE COURT: Well, we should get the answer to the Losartan issue today, but I think it does make sense one ESI protocol, but if there was one take away you're going to get this morning and this afternoon is the Court is very sensitive to the issue about peripheral defendants --

MR. SMITH: Hm-hmm.

THE COURT: -- and we want to protect their interests and we don't want them to be dragged along in this litigation when they don't belong -- they shouldn't be here. So that's an issue the Court is very sensitive to.

The ESI protocol is separate from what discovery they have to produce, if any. But it does make sense -- I understand your practical concerns, but it does make sense to only have one ESI protocol.

MR. SMITH: I completely agree, Your Honor, with that. But if you take a retailer say for example who may have substantial data as to sales or something along those lines, that retailer now has to look at every one of these ESI protocol requirements --

THE COURT: Okay.

MR. SMITH: -- to make sure that they can comply with it all when -- when really they're not the core defendant in the case, they're an ancillary defendant. So I -- I do agree with you though that one ESI protocol makes sense.

THE COURT: But you also have to concede that ultimately plaintiffs will need some discovery from those people if they're going to be -- you know, the ascertainability issue with regard to class certification and maybe identification of class members --

MR. SMITH: I would --

THE COURT: -- at some time in the case.

MR. SMITH: I would certainly agree, Your Honor, there are defendants who don't belong in this room but may very well have discovery that they would produce, but requiring them to go through all of this -- all of these protocols and all of the rest of the -- of the core discovery issues and all the rest when they should be let out at an early stage doesn't make sense to me.

MR. SLATER: Yeah, I think we'll probably be able to

resolve this, or at least tee up whatever narrow dispute we have and I'd expect there would be very few on this subject we're talking about.

By the end of the month, I would assume we could meet and confer and once you give a response we'll get conference calls going. I just one to clarify one thing. The people that have been -- the entities that have been sued, the repackagers, the retail server, they have liability --

THE COURT: Oh, yes.

MR. SLATER: -- so I want to just be clear for the record, they had obligations to inspect and audit and make sure they were selling clean drugs, I mean, to make it very simple.

I mean, so there the question is -- and I think as Judge Kugler and you are presenting it, is do they need to be active everyday defendants at this stage of the litigation.

And I know that my colleagues are ready to talk to the defendants during the break about certain things that we would want in order to say okay, if you can give us these things, we can agree to a dismissal without prejudice but we're going to want to have a line to you and we're going to -- obviously we're going to need to see the indemnification agreements and the supplies and figure out how everything fits together, with the right to bring them back in and so that we're not prejudiced, that's all fine.

But the -- and if there's some small entity that

doesn't get out of the case for whatever reason and says well, I don't want to have to PDF my document and, you know, and -- you know, put the metadata together for the plaintiffs through a vendor or whatever, I mean if it's a real burden, they'll come to Your Honor and say we're producing 20,000 documents, it's not that much, can we produce it under this subsection of the ESI protocol. It's nothing to hold things up I don't think.

I mean, ultimately the ESI protocol is driven by the overall litigation and I think the main players are the ones that will drive this so I don't think it's something that we have to worry about, the smaller defendants really, because I think from a practical matter, that's not going to be a major issue.

And if there is a specific unique to a defendant, they'll call us up, we'll talk about it and most likely we'll figure it out.

THE COURT: Good. Okay, the next issue, the protective order -- what we call in New Jersey a discovery confidentiality order, that should be an easy one.

MS. COHEN: Your Honor, Lori Cohen again on behalf of the defendants, I think right now just to use another great metaphor, I think the ball is in the plaintiff's court on this. We're waiting to get their feedback as noted in the joint statement.

We've provided the latest version to them on April 19th and just some background here -- I think Your Honor knows this from our prior appearance as well as our prior call, we initially took the District of New Jersey form and the Benicar form, came up with a version that we ran by -- you know, whatever number it is, 40-or-so, so we started there. That was the first version.

Then the plaintiffs said no, we're not willing to look at that, we want the Benicar only. They sent us one back so again, we were two ships passing in the night. Then we had our good productive call with you on I think it was April 10th and you said -- you know, you sort of encouraged us to rethink that.

So after the call I said okay, we're going to take it on the chin so to speak and go back to the whole group and we will use Benicar, redo it and send it to you. And so we did that and now we're just waiting for their comments.

THE COURT: Okay.

MS. COHEN: And so that's been the history. We've basically done three different versions, but we heard you and we presented to them and we're waiting to hear back from them now.

THE COURT: Can we target our phone call in two weeks to get this resolved?

MS. COHEN: Hm-hmm.

MR. SLATER: Absolutely.

THE COURT: Okay.

MR. SLATER: You know what, we'll do it then. Nothing to talk about.

THE COURT: Nothing to talk about.

MR. SLATER: Our positions are reserved.

THE COURT: And I want to give plaintiffs and defendants some comfort with regard to this DCO. We're not talking about sealing right now because that is Rule 5.3 -- Local Rule 5.3. But I don't want to put the cart before the horse.

Typically there are provisions in the DCO about stamping documents "confidential" or whatever. That is a different issue if there's a challenge to confidentiality. So I'm very sensitive to the confidentiality, you've read my opinions. If something is genuinely confidential, it will be confidential.

But if a document is embarrassing or someone doesn't want it to get in discovery or the press to get it, that's not a good grounds to stamp something confidential or, God forbid, "attorneys' eyes only," which is a much higher standard.

So I know plaintiffs always typically get very concerned about these confidentiality provisions, but it really shouldn't be a concern until they start stamping their documents. Then we'll deal with the issue.

And if someone over-designates, there will be consequences for it and in my experience, it works out at the end of the day.

Common benefit order. We got the order from the plaintiffs, we went over it, we have some very very minor tweaks. But we are going to add a provision that is substantive.

We're going to ask the plaintiffs to retain an accountant/CPA professional early and we're going to require quarterly reports to the Court in camera so that when Judge Kugler eventually has to decide the common benefit percentage, he will have the relevant information he needs to evaluate that application.

We did not do that in Benicar and on reflection, we probably should have and we've looked at other cases, but we think that protects everybody and will avoid disputes in the end. So we're just going to add that one substantive provision and some very minor tweaks that aren't material, and you'll get that probably this week.

MR. SLATER: That's great. We welcome that and we all talked also about potentially -- it's not in the order but it's something we're talking about, having the time submissions and expenses reviewed and it will fit perfectly with what Your Honor just stated so that if there are errors or issues, we can pick them up early and clean them up as we go as opposed to at

the end of the process.

THE COURT: Right. In X years when this case is over and if there is a common benefit fund to distribute, you'll be appreciative that we put this work in and early.

MR. SLATER: Just strike the word "if" and put "when," please.

THE COURT: Master complaints, we'll talk about that this afternoon. You said State Court discovery. Is there any State Court discovery?

MR. GOLDBERG: Your Honor, there's -- right now there's one State Court case. It's a case called Luno (phonetic). Discovery has been served in that case. That case is --

THE COURT: Where is that pending?

MR. GOLDBERG: That case is pending in Middlesex County, New Jersey.

THE COURT: Really?

MR. GOLDBERG: Yeah.

THE COURT: Is it one of the plaintiff's attorneys from this case?

MR. GOLDBERG: Yes. Well one of the -- Mr. -- you want to --

MR. ZEMORA: Judge, I'm Mark Zemora (phonetic). I'm sitting in for Mr. Orlando (phonetic) so I think it's my turn in the hot seat. We have the Rino (phonetic) case has been

filed and served in Middlesex and there's also the Orlowski (phonetic), who plaintiffs have been filed and served in the same county, unrelated case.

Discovery was propounded I believe in the end of March. I haven't pro haced into that case, Your Honor, since I'm standing in for Mr. Orlando, and Seth and I are talking about Fort Nation (phonetic), also one of the core issues, and we just met five minutes before Your Honor's hearing so and we'll keep talking to sort of dance under one --

THE COURT: Why is that case not in Federal Court?

MR. ZEMORA: You'd have to ask Mr. Orlando. I've been on the case about a week.

THE COURT: Does the Judge in that case know about this MDL?

MR. ZEMORA: I can't speak to that.

MR. GOLDBERG: Your Honor, I'm going to -- I'll -- you've spoken then, Mr. Zemora, we're -- we're talking so we're as liaison, I anticipate and expect to be coordinating with them with that case as well and -- and other cases and, Judge, you're going to have issues with lack of diversity in some cases, personal injury cases, and obviously if you can sue New Jersey defendants like CHP in New Jersey, they can't remove so there will probably be some number of cases in New Jersey I would expect at some point.

THE COURT: Is that an individual BI/PI case or is it

a class action that can --

UNIDENTIFIED SPEAKER: Individual.

THE COURT: Okay.

UNIDENTIFIED SPEAKER: Both of them.

THE COURT: Okay.

MR. GOLDBERG: And, Your Honor, we certainly expect to reach an agreement with them or coordinating any discovery in that case with this and we'll be back to Your Honor if we're not able to reach an agreement.

THE COURT: Okay. Document repository. Plaintiffs seem to be okay. The Court is going to require the defendants to get a document repository together. I just can't envision for example when one of the plaintiffs has to answer discovery that they're going to have to serve 50 different people.

When the plaintiffs are going to -- when medical records are produced, I -- it's just inconceivable that they'll have to send copies to 40 or 50 different people. There should be one repository for the defendants that you all could go to get copies of the documents.

MR. GOLDBERG: I think, Your Honor, the idea of receiving their discovery and potentially having it come into the document repository is something we haven't talked about but makes sense. From the standpoint of our producing information, we don't -- as separate entities with different sets of documents --

THE COURT: No, no, we have to work that out, Mr. Goldberg. There's 40 or 50 parties behind you. What are you going to do, produce 40 or 50 different copies to each of the defendants of your discovery?

MR. GOLDBERG: Well, we would produce -- each of our defendants would produce to their repository.

THE COURT: Well, what about the other defendants in the case?

MR. GOLDBERG: They would also produce to -- if they are required to produce documents --

THE COURT: No, no, no, no, no.

MR. GOLDBERG: -- from their --

THE COURT: The people behind you have a right to see your discovery. How do they get that? How do they get that? They can't get that unless it's in the repository or when your clients serve discovery, they're going to send a copy to 50 different people?

MR. GOLDBERG: Okay, I mean, I think we haven't discussed that. But let us discuss that and figure that out because that is an issue with respect to confidentiality so I mean --

THE COURT: I'm sensitive to the concerns.

MR. GOLDBERG: Yeah, so let us discuss that because that -- that obviously makes plenty of sense, we don't want to be producing 40 sets of everything.

THE COURT: Yes, there has to be some sort of repository.

MR. GOLDBERG: Let us visit on that and we'll get back to Your Honor on that.

THE COURT: Plaintiffs are going to produce one copy of their medical records. Aren't you going to have a repository where every defendant who wants to see those records can see them?

MR. GOLDBERG: That I think -- as I -- as I said, receiving their documents, plaintiff's documents into one repository makes sense. The question is whether we produce documents into a repository that then gets produced to them, that we have one vendor let's say that would control all of the defendant's documents, we haven't discussed that.

That doesn't seem to be something that we -- you know, at least at this point we would want to make sure whatever we're doing is respecting the questions of confidentiality as between competitors so let us visit on that and see if we can come up with some kind of --

THE COURT: Okay.

MR. GOLDBERG: -- efficient solution.

THE COURT: Also keep in mind that, you know, pick a number, if your client produces 100 documents, maybe only 25 of those are genuinely confidential that you don't want a co-defendant to see, so somehow a vendor can segregate those

somehow, some way. I don't know how but not a hundred percent of your client's documents will -- will need to be protected from the other competitors.

MR. GOLDBERG: Understood.

THE COURT: Okay.

UNIDENTIFIED SPEAKER: Your Honor, if I can just add to that briefly, I think in other cases where we have multiple defendants who are -- you know, many of us who were involved, we would have a depository as Mr. Goldberg said on the plaintiff's side where we can all receive their documents.

One the defense side, some of the companies have their own preferred vendors, and I think that's the issue that we're dealing with.

We'll have to figure that out and we can talk amongst ourselves whether, you know, we would share them and maybe have dividers as you're saying, have things kind of separated and maybe there can be some -- some sharing of that.

But a lot of times in other multi-defendant situations there are multiple defense vendors and it's worked out. There hasn't been an issue but we'll continue to discuss it.

THE COURT: I don't know about that. It seems impractical. But --

UNIDENTIFIED SPEAKER: Okay.

THE COURT: -- we're open to what works.

MR. PAREKH: Your Honor?

THE COURT: Yes.

MR. PAREKH: I'm Behram Parekh. From the plaintiff's side -- and we haven't discussed this in detail, but we intend to have a plaintiff's side repository for plaintiff documents to which we will issue user ID and passwords to all defendants so that there's one location where they can get medical records and all of that from. They don't need to set one up separately.

THE COURT: Great idea. Inclusion of non-manufacturer defendants. You're going to discuss that over the break, right? Okay. So let's get to the core document issue. The Court's position is there should be a middle ground between what plaintiffs are asking for and what defendants want to produce.

What was most interesting to me, plaintiffs, was defendants -- I have your April 16 letter -- defendants represent that the documents you request in two, three, four, five, six, seven and eight will be encompassed within what they agreed to produce. If that's true, do we really have a dispute here?

MR. SLATER: Again, the word "if" is a wonderful word but if it turns out -- if they produce it to us, we're happy. Whatever they call that production, if they say it's the ANDA file or the drug master file or the communications with the

FDA, that's wonderful if it's all there.

We have a meet and confer on Monday as I said before, and what -- when we started to ask some specific questions, we couldn't get answers unfortunately.

What it started to become was well, the pertinent information that you need is there. For example, there's going to be information about inspections. Well, all the inspections? Can't tell you that.

Then we said well, let me ask you something, when you're making this production do you intend to catalogue for us and make the production.

Like for example, request number two, we've produced this giant document dump, the documents responsive to request two are found in these base ranges. No, we don't need to do that.

So the net net of the call and our take away was we've told you what we're going to provide to you and what we're going to give you, we're not willing to respond to any of these specific requests even though we're telling you those things are going to be there anyway so it -- it was circular.

So from our perspective, since we think these are reasonable core requests, and again, Your Honor understand what we're trying to do, we don't know what the documents are called, we don't know how -- we haven't seen any documents, we haven't spoken to them about what's your department for this,

how are these documents titled, so we described the categories of information as best we could.

I don't think there can be a reasonable dispute that those -- we'll start with those categories two to eight, are core important issues because they're agreeing they're producing that information anyway. So what I think they need to do is give it to us.

And to the extent it's found in those three categories of documents that they've already agreed to give us, great, they should tell us where they are.

And to the extent they need to supplement that with the additional documents that would complete providing information to us, they should be able to do that and we took to heart what Your Honor told us about what they should be able to identify and provide to us without too much heavy lifting at this stage.

And for example, they say well, nine years of inspections reports, oh my gosh. Well, the FDA regulations require them to have all the inspections reports in a neat file that they can -- that if the FDA walked in, it's sitting there waiting for them.

So if they haven't done it, I guess this will be good, the case will get them to do it. So, I mean, most of these things they're supposed to have, if not all these things, in an organized fashion easily produced.

I'll give you another example which is not in those eight categories, but there's certain very narrow sales information because we obviously have some plaintiffs that the most important thing to them is what was sold, how much was sold.

Their marketing departments have day-to-day information about everything they've ever sold of these drugs. They know where they've sold it, how much they made, they -- they have it down to the penny of net, gross, et cetera. That's easy to press a button and provide also.

Now, if they say well that's going to take a little longer, okay, we don't care so take 60 days for that, give us the other things in 30 days or whatever timeframes Your Honor comes up with.

We've told them from day one if you want to roll this and you want to stage a couple of these categories, no problem. I mean, there's only so much we can review in one day anyway. But, you know, coming to the core issue, they agreed to produce ANDA, master drug file, all communications with the FDA. Great. If that encompasses --

THE COURT: All communications with the FDA regarding the recall.

MR. SLATER: Right, of course. Not -- not in history, no. Anything I'm talking about is within the context of this case for the record obviously. The contamination

issue.

THE COURT: But that's an interesting question. Would, for example -- this occurred to me -- their agreement to produce documents regarding the recall include documents regarding the investigation as to what caused this contamination?

MR. SLATER: That's one of our core requests.

THE COURT: I don't know.

MR. SLATER: They haven't -- and they -- I think they've agreed they'll produce those things. They've told us that's in their communications with the FDA.

I think that -- you know, that's three, four, five -- I mean it goes -- it's encompassed within these various categories because they're -- they're legally obligated to do investigations and we've also taken the timeframe back before the manufacturing process was changed.

Because again, they're supposed to have all that data in an organized fashion in -- I'm going to call it the file cabinet, wherever it's housed, and a very important issue in this case is going to be what were you seeing in terms of impurities before you changed the manufacturing process versus after.

That's going to be a very important indicator and that's something they have in their files. They -- unless they haven't done what they're supposed to do, they've been testing

their samples from their API and from their finished drug manufacturing facilities the entire time they've sold these things.

And to the extent that inspections are done, that should be in one place. So again, this is the core of the case and again, that's easily produced if they followed FDA regulations.

THE COURT: Did the defendants get their approval from the FDA in 2010?

MR. GOLDBERG: It depends on -- it depends on the defendant. For instance, ZHP's approval was in 2012 I believe.

THE COURT: Okay. The earliest one was 2010?

MR. GOLDBERG: ZHP's is 2010.

THE COURT: Okay. So the others may have been later, but no one was earlier. Do I take that?

MR. GOLDBERG: I think that's correct, Your Honor.

THE COURT: Okay. Do you want to add something, Mr. Goldberg?

MR. GOLDBERG: Yeah. Can I respond, Your Honor? I think the question about 2010, you know, what we -- what we have proposed to produce, the drug master file and the ANDA and the FDA correspondence relating to the recall, these were class two through eight are subsumed in that -- in those documents subject to some qualifiers.

I mean, we do not envision at this point producing

documents for core discovery back through 2010. For example, there would be really no basis to produce all inspection reports at any of these manufacturers going back to 2010. These companies manufacturer multiple drugs, many more than just Valsartan.

They have been doing so for many years, they distribute them in the US, they distribute them foreign. The way the requests are phrased, these requests would be picking up inspection reports that have nothing to do with the impurities at issue.

THE COURT: So suppose they ask for FDA inspection reports going back to 2010 that address Valsartan. What's wrong with that?

MR. GOLDBERG: There are -- because that would then -- that would be incredibly broad potentially --

THE COURT: Why?

MR. GOLDBERG: Because not every Valsartan inspection, not every inspection of one of these facilities where Valsartan is manufactured will have information relevant to the impurities that are at issue here. For instance --

THE COURT: Can you tell me how many inspections were done from 2010 to present?

MR. GOLDBERG: I don't know how many inspections.

THE COURT: So how can you argue it's burdensome if you don't know how many were done?

MR. GOLDBERG: I'm not arguing the question of burdensome, I'm arguing the question of relevance because I think that obviously ties to proportionality. I mean, if somebody dropped a vial in a manufacturing facility in 2012, that had nothing to do with the impurities at issue here, and that could be a rabbit hole. This is just for the purpose of core discovery.

THE COURT: But, Mr. Goldberg, if the FDA does an inspection in 2010, 2011 to see if a foreign facility complies with current good manufacturing practices, wouldn't that be relevant to this case?

MR. GOLDBERG: It may or it may not, but it's not the issue for core discovery. What we understood Your Honor to be saying with respect to core discovery was unquestionably relevant.

THE COURT: Right.

MR. GOLDBERG: That -- no, a CGMP in 2010 or 2011, if we were found to be out of CGMP for an issue that has nothing to do with the NDMA impurities would not be unquestionably relevant. It would -- and there could be many of those instances. They could pertain to many drugs. But the point is to even get there, there would have to potentially be -- those documents may not be easily retrievable.

THE COURT: Can you tell me if they are or you don't know? That's a fair statement, right? So we can't argue

burdensome at this argument because you don't know the answers to the -- I'm not faulting you.

I'm not faulting you. But please don't argue burdensomeness without the background information to support the argument. If FDA did an inspection once every two years and it's 2019 and they start in 2020, we're talking about five reports?

MR. GOLDBERG: We don't -- we don't know --

THE COURT: Right.

MR. GOLDBERG: -- the volume of the information but what we do know is what Your Honor wants to do with respect to core discovery, I mean, that's the dividing line. There has to be a demarcation. It can't swallow with the rule here and I -- what we're talking about --

THE COURT: So might --

MR. GOLDBERG: -- is the FDA --

THE COURT: -- the demarcation be, Mr. Goldberg, that we're going to limit plaintiff to FDA inspection reports and we're going to put aside for a later day the argument whether they get EU or Bolivia reports and Canada reports, et cetera.

MR. GOLDBERG: That's a fair line of demarcation, but then the question is are we going to limit it to Valsartan, are we going to limit it to a certain impurity like NDMA, NDEA because impurities are allowed. There are thresholds of impurities that are -- what I'm --

THE COURT: I know, but we --

MR. GOLDBERG: -- what I'm suggesting, Your Honor, is that we --

THE COURT: We can't limit it to NDEA because they only discovered it in 2018, right?

MR. GOLDBERG: And for the purpose of core discovery, how the impurities occur, that's what we're getting at and what we don't want to do is go down a rabbit hole of other impurities, other issues.

I mean, we can and we have made a very good effort to compile information that is directly responsive to the question how did these impurities occur. It -- the drug master file, it's not just -- it's not a shell, neither is the ANDA.

You're getting real substantive information about how these drugs are made, the processes, what goes into them, the excipients, the standard operating procedures. The testing, there is testing information in all of these journals, the articles, the equipment.

It's all in the drug master file. It's in the ANDA. And then what we're proposing with respect to the FDA correspondence so that we don't go down rabbit holes from 2011, '12, '13, '14, '15, '16 and '17, what we are proposing is the FDA correspondence that relates directly to how the impurities occurred.

And I can tell you that the FDA is not investigating

with respect to the impurities at issue things that happened in 2012 and 2010 that have nothing to do with Valsartan or the process that could have resulted in the impurities.

If there's testing that these defendants have done in response to -- in response to questions by the FDA as a result of the recalls, it's in there. If there are corrective actions that have been proposed, it's in there.

That's where we think core discovery, you know, really needs to happen. That's the line of demarcation and an important way because it can be done without ESI protocols, it can be done without the identification of custodians.

Importantly, some of the underlying information -- and I want to be clear because when we're talking about an FDA communication, there will be resultive tests, there will be studies, but some of that stuff is happening in China or in India.

Core discovery of those underlying documents, that would be -- you know, that would really be anathema to the idea of core discovery. We want to provide the FDA correspondence, whatever the FDA is looking at, whatever the companies are providing to demonstrate how the impurity occurred, what they're doing to solve it so they can get back to market. Those are the real issues here.

If we have to go and, you know, talking about easily retrievable which is the words that Your Honor used a few weeks

ago, getting to some of the underlying documents in China, we will be doing core discovery until potentially this thing turns into merits discovery and we -- we understand Your Honor to wanting to get plaintiff's information within the next, you know, 60 to 90 days and that's what we have endeavored to do.

And our suggestion is requests two though eight are subsumed in what we're going to provide subject to date limitation, subject to drug limitation, subject to impurity limitation because that's what's at issue here, that we produce that stuff and we're prepared to produce it soon.

We're collecting it, and then if there's some other issue, if there's some specific document, there's some specific FDA inspection report, that because of the core discovery plaintiffs say hey, you know what, we need this document in core discovery, we need to meet with this witness in core discovery -- I don't want to throw out witnesses at this point but -- but that's the idea that we -- we understand the Court for wanting to do, is to get this thing moving by really getting at the critical information. And that's the DMF, the ANDA and the communications with FDA on this very issue.

THE COURT: Did you want to add something, Mr. Slater?

MR. SLATER: You know what, actually did you want to add --

UNIDENTIFIED SPEAKER: In the interest of time, Your

Honor, lab testing goes to the heart of how this recall occurred, and so on our meet and confer on Monday I asked the defendants well, what if there's lab testing that's important, it shows some signal of an impurity, but it wasn't turned over to the FDA, would we get that at this stage.

And their answer was no. Undeniably no, you'll get that sometime later. So to us, that is the -- one of the core issues and also another -- it doesn't require an ESI protocol. ESI protocol won't handle that issue. We handle that individually.

THE COURT: How would you ask for that document or documents? You'd say what, get me all testing results?

UNIDENTIFIED SPEAKER: Yeah, all lab testing results regarding Valsartan and the key is I noticed another issue that they -- they stated -- subject to this impurity -- well that's the other problem. You're not -- you're not seeing it from NDMA or NBEA, that only becomes alarmed according to the announcements in 2018. So in other words, we're not going to get the documents as to how this occurred because it's the signals that are going to show us, it's not NDMA or NBEA itself, other signals, and that's why we want the testing of all Valsartan pills at this stage.

THE COURT: I'm not envisioning full merits discovery at this early stage. We're going to get to those issues in the case. So even if the Court doesn't consider this core, it

doesn't mean you don't get it in discovery.

MR. SLATER: Your Honor, just to make it clear, our request five is all these results of testing for impurities of API and finished product going back to 2010. Now, what we were trying to have in the meet and confer was so okay, let's go through our requests, tell us if you agree to something, yes.

If not, where is the issue and let's try to figure out language that we can work through and we couldn't have that conversation and you can see what's happening now. This is an example of how kind of how the call went.

So for example, we don't care about a vial dropping on the floor obviously, so if they want to tell us they're going to give us -- which they have in file cabinets pursuant to FDA and other regulations across the world for testing of the API that came out of those plants -- that's what we asked for.

That's what we want, we want the testing because as you'll see, Your Honor, as this case goes forward and the FDA, it's great that they finally caught onto this thing after years of not catching on but there's a reason perhaps that the FDA doesn't want to go back in time because on the testing, certain impurities are seen and they're not -- it doesn't say NDMA on it, you have to dig deeper.

And one of the big problems here is we think things were showing up and being ignored and, you know, the question

is I don't know the state of mind on the "ignoring," it's not for today to argue.

But really what the FDA wants and what they've told the FDA is really -- it's such a tip of the iceberg and core is they have in their files what they did when they tested the APIs as they came off the assembly line. They have to test it, they've been doing it.

They have to put it in one organized file and they should be easily able to produce it. That's why the FDA communications when we said well what's in there and we kept hearing well what's pertinent to you is in there, it's so easy to produce what we're asking for and you know, respectfully I think it should be ordered.

We're certainly not going to dictate to the Court what core discovery means. It's whatever Your Honor says it means and we'll live with whatever you say and I think we can defend any of these requests. For example, the first one, that came out of Judge Kugler's mouth at the case management conference, get us the communications with foreign regulatory agencies as well.

It's in the transcript. You know, he mentioned it so we're not sure why that's -- why they're arguing about those communications when we thought that was understood, and we're happy to talk through the rest of the issues to the extent we need to, Your Honor.

THE COURT: Mr. Goldberg, last word.

MR. GOLDBERG: Your Honor, it may be the tip of the iceberg. That's the point of core discovery. This is a chance to get to the core issues. A thing like testing is a good example. These manufacturers -- and the way number five is written and Mr. Slater just said it, they want all testing as to all APIs. Well guess what, ZHP makes 50 or so APIs so clearly --

MR. SLATER: So narrow it for today.

MR. GOLDBERG: Clearly not core discovery. They test for solubility, they test for strength, they test for stability. These are not issues that are the subject of core discovery. I fully expect that the FDA correspondence that the parties have exchanged with the FDA on the NDMA and NDEA impurities deal with questions what kinds of testing has been done to determine whether those impurities exist, what kinds of testing can be done.

And the FDA has not even been able to figure out -- or took -- or it took the FDA a while to figure out a test for these substances. But you're talking now about almost a year's worth of communications with the FDA. They're taking this investigation very seriously.

They haven't issued statement after statement because they're turning a blind eye to this. They are requiring the manufacturers to produce significantly amounts of material

information and we in turn are offering to produce that very same material information in core discovery.

That should be the line of demarcation. If there's a specific document they identify after looking at that core discovery that they want us to supplement our core discovery with, maybe that makes sense to do.

It may be that by the time they review this information we're further along in this case, we've lost some defendants, we're closer to merits discovery.

Some of these issues that plaintiffs are raising now may be the subject of merit discovery or maybe we'll have realized that all of those issues are really irrelevant because the FDA has done a very good job of requiring the manufacturers to bone up on this and to produce the real critical information.

THE COURT: Thank you, Mr. Goldberg. Let me tell you what the Court thinks. The Court's criteria for what it calls core discovery is one, easily identifiable information. You said it very well, Mr. Goldberg, you don't need ESI search terms to get it. Unquestionably relevant and not privileged material, easily retrievable and a discrete set of documents. That is the Court's criteria for core discovery, okay?

With regard to whether the plaintiff gets just FDA or communications with all regulatory authorities for the time being, we're just going to leave it to the FDA.

No information has been presented to the Court to indicate thus far that there's anything in these -- that these other regulatory bodies would have that the FDA wouldn't.

I 100 percent believe that this issue is going to be teed up on a discovery dispute sometime in the case and we'll brief it. We'll deal with it and we'll deal with the proportionality argument.

I'm not saying it's not discoverable under Rule 26, I'm just saying for core discovery purposes, we're just going to focus on the FDA.

With regard to two through eight, I'm going to take the defendants at their word and let defendants see -- let plaintiffs see what defendants produce and what's missing.

I'm going to deny the request for nine, ten and 11. I don't think that's within the Court's definition of core at this point. The following additional information will be ordered to be produced.

One, I'm going to draft an order to this effect and mirror a provision in the Local Court's patent rules. There is a provision in the Local Court's patent rules where the defendant is required to, without a specific request for the information, send to the plaintiff correspondence with the FDA.

So defendants are going to have to periodically update their production to keep the plaintiffs up to date on the correspondence with the FDA and all I'm going to do is

mirror the local patent rule.

I'm going to order the defendants to produce all FDA inspection reports going back to 2010, all 483s, all warning letters and all establishment inspection reports or however they word it.

Again, in the Court's view these are easily identifiable discreet sets of clearly relevant, unquestionably relevant documents. FDA CGMP inspections are going to have to be produced. My understanding is there's not that many of them.

Maybe -- I don't know, I don't envision they do these inspections every week or every month and it's inconceivable to me that the parties don't have a folder on the computer or in a file cabinet where they don't have these reports together.

I want to clarify the defendant's agreement to produce FDA correspondence regarding the recall. I assume that includes any discussion regarding how and why these impurities occurred rather than just the recall itself. I think that's what defendants meant but it's going to be clarified -- intended, but it's going to be clarified.

I'm going to order those documents to be produced within 45 days and then by the next conference, I want to find out if those companies who aren't quite sure if they're going to produce the foreign documents are going to produce them or not.

I guess that's Hetero and Aurobindo, and it will just be in the order. I think that's a fair compromise. We can agree to disagree, Mr. Goldberg, but I do think FDA inspection reports are unquestionably relevant going back to day one.

MR. GOLDBERG: Yeah, Your Honor, just to --

THE COURT: Regarding Valsartan.

MR. GOLDBERG: That's -- yeah --

THE COURT: Yes.

MR. GOLDBERG: I just wanted to clarify because --

THE COURT: Yes, yes, yes, yes, regarding Valsartan. Not the inspection -- the inspection reports regarding the facility, the 483s, they're relevant even if they don't specifically mention Valsartan because it goes to whether good manufacturing practices were followed or not. That's a gigantic part of plaintiff's case. It's clearly relevant.

MR. GOLDBERG: Again, agree to disagree but I just -- a clarifying point on that, there are some facilities where Valsartan is manufactured and some that aren't.

THE COURT: I'm going to draft the order, clearly there's no -- we're not worried about facilities that don't manufacture Valsartan. I wouldn't put that -- I'm going to clarify that we're going to focus on Valsartan.

MR. GOLDBERG: And then I just have two -- a couple of followup questions on this so that the order can be as clear as possible. When we're talking about 483s and inspection

reports, are you talking about communications with the FDA after the report, following up on the report, because again, you're getting potentially --

THE COURT: Well it's --

MR. GOLDBERG: -- and we don't know --

THE COURT: No --

MR. GOLDBERG: -- the issues to getting to some significant volume.

THE COURT: Well, it's my understanding that, you know, sometimes, sometimes not, "warning letters" are issued. That's what I'm talking about. I'm not saying every piece of paper regarding those inspections has to be produced because then we get into ESI issues.

MR. GOLDBERG: Right. That's what I wanted to clarify.

THE COURT: That's different. I wouldn't put that in the category of discreet easily identifiable information, although eventually it's going to be produced because it's clearly relevant. But I wouldn't put that in the category of core. What I was hoping was plaintiff was going to give me names of specific types of documents they wanted like if there was a test report that was required to be produced that had a name, I would be amenable to ordering that to be produced, but we don't have that.

Just producing all inspection reports I think is

broad -- too broad at this stage of the case. Eventually you may get them but I wouldn't -- I don't think that fits within my definition.

MR. GOLDBERG: Losartan and Irbesartan.

THE COURT: Well, let's talk about that. Good question. As I understand it, at least from the letter, it's out of the case, but then I saw the recall a few days ago so I don't know what the plaintiff's position is.

MR. SLATER: Your Honor, it's the -- in looking at the recent recall, another over 100,000 pills, we're continuing to see that the recall is obviously building in terms of the numbers of Losartan cases.

We've confirmed with this on our side, we believe that it is just a matter of time until we're going to be making a petition in front of the JPML for those cases to be consolidated here in both Losartan and Irbesartan.

THE COURT: When you prepare your master complaint, is there going to be a sartan in the complaints other than Valsartan?

MR. SLATER: I don't believe so, not for the first master complaint.

THE COURT: So does that answer your question?

MR. GOLDBERG: Yeah, we don't believe that that should be part of core discovery though.

THE COURT: You know, we're only talking about

Valsartan.

MR. GOLDBERG: Correct.

MR. SMITH: Your Honor, if I may, Richard Smith, just putting on my hat for the minor defendants, two things. Can we clarify in the order that the discovery order applies only to the ABI (sic) manufacturers and the finished dose manufacturers? You gave --

THE COURT: I think the answer to that question is I wouldn't envision that anyone else would have responsive documents.

MR. SMITH: So it is possible that a -- a retailer -- an attorney at a retailer may have opened a file and had been printing things off the internet that -- that they may have put in a file and I would not want to put that retailer in jeopardy of violating an order such as this, even -- even a business may have done that who has responsibility for purchasing Valsartan.

THE COURT: So API manufacturer/supplier or a finished product manufacturer, that's who you want to limit it to?

MR. SMITH: Yes, Your Honor.

THE COURT: Any objection at this stage?

MR. SLATER: My only question would be would a supplier include Solco? Is that -- at that level, is Solco a supplier?

MR. GOLDBERG: Right, these documents are coming from

the FDA liaison, Prinston. I mean, Solco is not in the position of being an API manufacturer or finished dose manufacturer so but these documents are coming from ZHP through --

THE COURT: Would Solco have anything that -- they're in the ZHG chain?

MR. NIGH: Would they have anything that ZHP wouldn't have? That's our question because they're a big company and they're a direct subsidiary.

MR. GOLDBERG: Not on -- not on these issues. I mean, these issues are getting to the FDA issues --

THE COURT: Yeah.

MR. GOLDBERG: -- and the manufacturing issues.

MR. NIGH: Well, I think my question is more geared towards not just Solco but it would be somebody like Camber who is a distributor but they don't have a finished supplier here in the US and so they have API and just finished supplier which is why we think the line should be drawn.

THE COURT: I think defendant's suggestion is a good one. We'll limit it to just the API manufacturer/suppliers and the finished product suppliers. At this time, obviously we're not ruling on Rule 26 discovery, Mr. Nigh.

MR. NIGH: Yes.

MR. SMITH: Your Honor, one -- one other request. Again, for the minor defendants, can we tie the production to a

number of days following the filing of the master complaints since I fully expect given the representation we've just heard from the plaintiffs that many of our defendants will fall out of this order.

THE COURT: You know, the train is leaving the station.

MR. SMITH: Well when I say that, Your Honor, we'll take for example Sandoz, which produces solely for purposes of this case Losartan.

THE COURT: Well, the order is going to be limited to Valsartan.

MR. SMITH: Okay. I appreciate that, Your Honor.

MR. SLATER: Your Honor, if I may, I forget which defendant said we may have a chicken and egg problem, the sort of another chicken and egg problem that I want to identify before we move away from core discovery.

The defendants in their position paper at page six for finished dose manufacturers expressed a willingness to provide us a list of customers to whom each manufacturer sells so that we could identify for example retailers and others from whom presumably plaintiffs purchased the product.

It occurs to us that to a certain extent we remain in the dark about the distribution chain and exactly how it is, and here's the chicken and egg part. We're very willing to let folks out of this case once we have some light shed on what the

distribution is.

So it occurred to us that if the finished dose manufacturers are willing to provide a list of customers, that that same sort of thing, that is from the API folks -- the API folks should say where the API traveled to, where they sold it to, what customers got it. It seems to me that it fits the definition of core and I'm -- I'm curious to know --

THE COURT: What timeframe?

MR. SLATER: I don't see a reason why 45 days wouldn't --

THE COURT: No, no, no, no, what timeframe for example --

MR. SLATER: Oh --

THE COURT: -- a list of customers to whom each manufacturer sells the finished dose.

MR. SLATER: I mean, I would say for both consistency and logical consistency, it would be the same. It would be from when they started selling -- putting Valsartan on the market.

MR. GOLDBERG: Your Honor, I -- we haven't addressed that issue anew, we should consider it and I do think that an appropriate limit or at a minimum would be in the US market, so I think we can consider that, we can discuss it with them and, you know, hopefully we can reach an agreement on that if that's something that is --

THE COURT: Sounds reasonable.

MR. SLATER: Yeah, that sounds reasonable to us too.

UNIDENTIFIED SPEAKER: Would that include that it was sold to a distributor that then -- where it then got to the US through that distributor? I assume it chains that get to the US, right?

MR. GOLDBERG: Let's talk about it.

MR. SLATER: We're agreed.

THE COURT: Help me help you. I'm going to draft the order, what should the order say?

MR. SLATER: I think if you look at page six of their letter --

THE COURT: I'm looking at it, but --

MR. SLATER: -- it would be the same phrase, you know, we'll just take their phrasing, a list of customers to whom each manufacturer sells and each API manufacturer sells Valsartan for ultimate sale in the US market.

MR. GOLDBERG: Now, I think we can provide from -- from API manufacturers a list, but as to US entities or as to the US market.

THE COURT: In other words, who the US customers are but how do they know if they sell it to a company in Bolivia whether or not they're going to get it to the US market?

MR. SLATER: We're fine with into the US for now. It's fine, it's a starting point. I'm sure we'll have

discussions about who they sold to and which distributors and then distributing in the US --

THE COURT: Right.

MR. SLATER: -- we'll figure that out. It's just --

THE COURT: That's a good place to start anyway.

MR. SLATER: And, Your Honor, I assume also your order -- the other things they've agreed to provide, the ANDA files and the master drug files, that would also I assume be included since they've agreed to provide those things?

THE COURT: Well, everything they agreed to produce is going to be part of the order, but okay, that way we have to get the DCO wrapped up, okay?

So let me go over my notes what we covered this morning and if I missed anything important, you'll let me know. Over the break hopefully the defendants are going to discuss whether it's necessary to expand the executive committee to make it more representative.

This afternoon we're going to deal with the service issue, that's a big issue. On the master complaint issue the defendants have a preference but no strong objection to plaintiff's three complaints. We're going to wrap up the profile forms no later than at the next conference at the end of May.

The ESI protocol disputes, we're going to tee up, if any in 30 days leaving search terms and custodians for another

day. The DCO, we'll hopefully wrap it up in our call in two weeks. The common benefit order you're going to get. The core order I'm going to enter, 45 days from the date of the order, produce the documents.

By the next conference, we'll know if Hetero and Aurobindo are going to respond to it. And then we're going to limit that order to the API manufacturer/suppliers and the finished product dose manufacturers and add the sales to the US market. Those are my key notes of what we covered this morning.

For the good of the order, anything -- anybody have any other issues you want to address before we break and you'll have time to hopefully get a bite and then we'll meet in courtroom 4D at 1:30.

MR. SMITH: Your Honor, would this courtroom be available for the defendants to meet?

THE COURT: Oh yeah, you could stay here and if you want to break up, you're welcome to use the jury room as well.

MR. SMITH: Thank you, Your Honor.

THE COURT: If anybody needs to sign in, I'll leave these up here. Yes, Mr. Trischler?

MR. TRISCHLER: Thank you, Your Honor, and everyone's stomachs are growling it seems so I won't be very long.

THE COURT: Wait til after they have lunch in Camden.

MR. TRISCHLER: I just wanted -- I just wanted to

raise a concern, I don't think it affects the order the Court is about to enter, but I want to at least raise a concern in case I have to come back for relief. I understand the Court's objective to get core discovery served within 45 days and we will certainly work to comply with that.

And as Your Honor mentioned, there are issues regarding the discovery confidentiality order that still needs to be resolved and depending upon the final wording of some of these documents like the establishment inspection reports, I know that some of these manufacturers and finished dose suppliers have multiple sites, we have multiple ANDAs.

And so it may not be very -- it may not be easy to collect documents from multiple sites and to review them and have them all ready to go in 45 days. I'm going to -- I'll certainly work to that objective, but if I -- if it's something that I wanted the Court to -- I wanted to point put out to the Court that perhaps at our next telephone conference in two weeks or at the next conference, I may raise this issue again and ask for some relief. But we'll work toward the 45 day window.

THE COURT: I think you'll find as we go forward in this case if there's good cause, the deadlines are going to be extended. So if there's a good reason to extend them, if you represent to us X, Y, Z, you need an extension, I don't think there will be a problem. Anything else?

Okay, see you in a few minutes.

COURTROOM DEPUTY: All rise.

(Matter concluded, 12:05 p.m.)

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C E R T I F I C A T I O N

I, Diane Gallagher, court approved transcriber, certify that the foregoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter.

Diane Gallagher Digitally signed by Diane Gallagher DN: cn=Diane Gallagher, o, ou, email=dianadoman@comcast.net, c=US Date: 2019.04.30 12:54:21 -04'00'

November 8, 2015

DIANE GALLAGHER DATE

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